

the injury occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. Temporal association between receipt of the countermeasure and onset of the injury is not sufficient by itself to prove that the countermeasure caused the injury.

(d) *Injuries resulting from the underlying condition for which the countermeasure was administered or used.* An injury sustained as the direct result of the covered condition or disease for which the countermeasure was administered or used, and not as the direct result of the administration or use of the covered countermeasure, is not a covered injury (*e.g.*, if the covered countermeasure is ineffective in treating or preventing the underlying condition or disease).

### Subpart D—Available Benefits

#### § 110.30 Benefits available to different categories of requesters under this Program.

(a) *Benefits available to injured countermeasure recipients.* A requester who is an injured countermeasure recipient may be eligible to receive either medical benefits or benefits for lost employment income, or both.

(b) *Benefits available to survivors.* A requester who is an eligible survivor of a deceased injured countermeasure recipient may be eligible to receive a death benefit if the death was caused by the covered injury or its health complications.

(c) *Benefits available to estates of deceased injured countermeasure recipients.* The estate of an otherwise eligible deceased injured countermeasure recipient may be eligible to receive medical benefits or benefits for lost employment income, or both, if such benefits were accrued during the deceased countermeasure recipient's lifetime, or at the time of death, as a result of a covered injury or its health complications, but have not yet been paid in full by the Program. Such medical benefits and benefits for lost employment income may be available regardless of the cause of death. The estate of the deceased injured countermeasure re-

cipient may not receive a death benefit. Death benefits are only available to certain survivors.

#### § 110.31 Medical benefits.

(a) Injured countermeasure recipients may receive payments or reimbursements for medical services and items that the Secretary determines to be reasonable and necessary to diagnose or treat a covered injury, or to diagnose, treat, or prevent the health complications of a covered injury. The Secretary may pay for such medical services and items in an effort to cure, counteract, or minimize the effects of any covered injury, or any health complication of a covered injury, or to give relief, reduce the degree or the period of disability, or aid in lessening the amount of benefits to a requester (*e.g.*, a surgical procedure that lessens the amount of time and expense for the treatment of a covered injury). The Secretary may make such payments or reimbursements if reasonable and necessary medical services and items have already been provided or if they are likely to be needed in the future. In making determinations about which medical services and items are reasonable and necessary, the Secretary may consider whether those medical services and items were prescribed or recommended by a healthcare provider, and may consider whether the applicable service or item is within the standard of care for that condition.

(b) To receive medical benefits for the health complications of a covered injury, a requester must demonstrate that the complications are the direct result of the covered injury. Examples of health complications include, but are not limited to, ill-effects that stem from the covered injury, an adverse reaction to a prescribed medication or as a result of a diagnostic test used in connection with a covered injury, or a complication of a surgical procedure used to treat a covered injury.

(c) The calculation of medical benefits available under this Program is described in § 110.80. Although there are no caps on medical benefits, the Secretary may limit payments to the

amounts that she determines are reasonable for services and items considered reasonable and necessary. All payment or reimbursement for medical services and items is secondary to any obligation of any third-party payer to pay for or provide such services or items to the requester. As provided in § 110.84, the Secretary retains the right to recover medical benefits paid by the Program to requesters if third-party payers are obligated to provide those benefits. Requesters are expected to make good faith efforts to pursue medical benefits and services from their primary payers. The Secretary reserves the right to disapprove medical benefits if the requester fails to do so.

(d) The Secretary may make payments of medical benefits or reimbursements of medical expenses described in this section to the estate of a deceased injured countermeasure recipient as long as such payments or expenses were accrued during the deceased injured countermeasure recipient's lifetime, or at the time of death, as the result of the covered injury or its health complications, and were not paid in full by the Program before the deceased injured countermeasure recipient died.

**§ 110.32 Benefits for lost employment income.**

(a) Requesters who are determined to be eligible for Program benefits as injured countermeasure recipients may be able to receive benefits for loss of employment income incurred as a result of a covered injury (or its health complications, as described in § 110.31(b)). Compensation for lost wages is paid as a percentage of the amount of employment income earned at the time of injury and lost as the result of the covered injury or its health complications. The period of time requested for lost employment income benefits must be supported by the severity of the covered injury as demonstrated by the medical and employment records.

(b) The method and amount of benefits for lost employment income are described in § 110.81. Benefits for lost employment income will be adjusted if there are fewer than ten days of lost employment income. Pursuant to law,

and as described in § 110.81, benefits provided for lost employment income may also be adjusted for annual and lifetime caps. Payment of benefits for lost employment income is secondary to any obligation of any third-party payer to pay for lost employment income or to provide disability or retirement benefits to the requester. It is the obligation of requesters to follow all specified procedures to apply for and acquire third-party benefits. The Secretary has the discretion to disapprove lost employment income benefits if the requester fails to do so. As provided in § 110.84, the Secretary reserves the right to recover lost employment income benefits paid by the Program to requesters if third-party payers are obligated to provide those benefits.

(c) The Secretary does not require an individual to use paid leave (*e.g.*, sick leave or vacation leave) for lost work days. However, if an individual uses paid leave for lost work days, the Secretary will not consider those days to be days of lost employment income unless the individual reimburses the employer for the paid leave taken and the employer restores the leave that was used. This puts the individual back in the same position as if he or she had not used paid leave for the lost work days.

(d) The Secretary may pay benefits for lost employment income to the estate of a deceased injured countermeasure recipient as long as such benefits were accrued during the deceased injured countermeasure recipient's lifetime as the result of a covered injury or its health complications, and were not paid in full by the Program before the deceased injured countermeasure recipient died. However, no such lost employment income may be paid after the receipt, by the survivor or survivors of a deceased injured countermeasure recipient, of death benefits under § 110.82.

**§ 110.33 Death benefits.**

(a) Eligible survivors may be able to receive a death benefit under this Program if the Secretary determines that an otherwise eligible countermeasure recipient sustained a covered injury and died as a direct result of the injury